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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,062	12/10/1999	TAO TAO	17634-00034U	9639

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NATIONAL INSTITUTES OF HEALTH
OFFICE OF TECHNOLOGY TRANSFER
6011 EXECUTIVE BLVD SUITE 325
ROCKVILLE, MD 20852-3804

EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/459,062

Applicant(s)

TAO ET AL.

Examiner

Stacy B. Chen

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See attached.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-10, 12, 14, 15, 17, 19-30 and 46-74.
Claim(s) withdrawn from consideration: 31-45.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

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Advisory Action

Applicant's after-final amendment filed August 18, 2006 is acknowledged and entered. Claims 1-10, 12, 14, 15, 17, 19-30 and 46-74 are pending and under examination. Claims 31-45 remain withdrawn from consideration, being drawn to non-elected subject matter.

The rejection of claims 11, 13 and 16-18 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is moot in view of the cancellation of claims 11, 13 and 16-18.

Claims 26 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of Applicant's persuasive arguments.

The provisional rejection of claims 1-30 and 46-74 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 144-215 of copending Application No. 09/083,793, is withdrawn in view of the terminal disclaimer filed August 18, 2006.

The provisional rejection of claims 1-30 and 46-74 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 53-85 of copending Application No. 09/458,813, is withdrawn in view of the terminal disclaimer filed August 18, 2006.

The provisional rejection of claims 1-30 and 46-74 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 85, 88-92, 94-96, 98, 99, 101, 104, 107, 108, 113-117, 119, 122-126, 128-130, 132, 133, 135, 140, 141, 146-152, 154,

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157, 159, 162 and 164 of copending Application No. 09/586,479, is withdrawn in view of the terminal disclaimer filed August 18, 2006.

The provisional rejection of claims 1-30 and 46-74 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 180-222 of copending Application No. 09/733,692, is withdrawn in view of the terminal disclaimer filed August 18, 2006.

Claim Rejections - 35 USC § 102

Claims 1-10, 12, 14, 15, 17, 19-30 and 46-74 remain rejected under 35 U.S.C. 102(e) as being anticipated by Belshe *et al.* (US 5,869,036, "Belshe"). The summary of claims and teachings of Belshe are of record.

The claims are directed to infectious chimeric PIVs having a human PIV background genome and a chimeric glycoprotein from another antigenically distinct HPIV. The claims indicate that a structural domain, antigenic domain or epitope of the heterologous gene (or encoded protein) is incorporated into the background genome. The Office recognizes that Applicant is interpreting the "chimeric glycoprotein" as a glycoprotein that has a portion of the background gene and a portion of the heterologous gene, but that neither the background gene or the heterologous gene is completely present in the chimeric gene encoding the chimeric glycoprotein. This inventive concept is not represented clearly in the claims. The problem remains that the claims are broadly written and thus read on Belshe's invention for two reasons:

1. Belshe's cp45 HPIV-3 hybrid virus has a HPIV-3 background genome and a glycoprotein from HPIV-2. The final product (a glycoprotein from HPIV-2 completely replaced

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with the corresponding glycoprotein from HPIV-3) is reasonably considered a “chimeric” glycoprotein. The glycoprotein from HPIV-2 is chimeric to the background HPIV-3 genome.

2. Given the interpretation discussed above, the claims’ recitation of “incorporating one or more heterologous structural domains, antigenic domains” of a second antigenically distinct HPIV read on Belshe’s glycoprotein exchange between cp45 HPIV-3 and HPIV-1 or 2. (Note that the exchange of single epitopes between HPIVs is not taught or suggested by Belshe.)

It is suggested that the identity of the “chimeric glycoprotein” be structurally defined in the claim in order to overcome this rejection.

With regard to Applicant’s remarks on “antigenically distinct”, the Office understands that Applicant appears to interpret the term as follows: Any antibody that binds to any epitope along and within the entirety of any wild-type HPIV-1 will never bind to any epitope along and within the entirety of any wild-type HPIV-2 or HPIV-3. The same applies to HPIV-2 in relation to HPIV-1 and HPIV-3; the same applies to HPIV-3 in relation to HPIV-1 and HPIV-2. While this understanding would clear up the scope of “antigenically distinct”, the specification does not appear to support this interpretation, nor would Applicant be able to prove such a concept. It is suggested that Applicant specifically name the antigenically distinct HPIVs, in a Markush group, for example, in order to clarify the scope of the term “antigenically distinct”.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 9/22/06
STACY B. CHEN
PRIMARY EXAMINER